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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CR-18-00258-EJD JOINT STATUS MEMORANDUM

The parties in the above-captioned matter hereby file this joint status memorandum in advance of the hearing set for July 17, 2019. Statements from the government (Section I) and from the defense (Section II) are set forth below.

I. Government's Statement

A. Current Status Regarding Agency Documents

In advance of the June 28, 2019 hearing on Defendants' Motion to Compel, the prosecution met and conferred with defense counsel regarding certain categories of documents Defendants believed were held by federal government agencies including the FDA, CMS, and the California Department of Public

Health (CDPH). During those discussions, government counsel informed defense counsel that the prosecution did not control the requested documents, but nonetheless offered to make efforts to obtain those documents from the agencies in question and produce them to the defense. Defendants rejected the government's offer and filed a motion to compel. Nevertheless, on May 9, 2019, the government sent letters to representatives of FDA and CMS requesting access to the specific categories of documents identified by Defendants. On June 28, 2019, the Court held a motion hearing where the government informed the Court of the status of those requests and the agencies' positions regarding production of the documents.

Following the hearing on June 28, 2019, the prosecution continued its efforts to obtain the requested materials from FDA and CMS. Government counsel urged the agencies to produce all requested documents as soon as possible and provided them with copies of the Court's June 28, 2019 order and a transcript of the motion hearing. The prosecution's discussions with the agencies focused on potential solutions to the issues preventing a prompt and complete production—in particular, the agencies' need for a protective order and a waiver from the Assignee controlling Theranos's right to trade secrets and confidential corporate information.

Accordingly, government counsel prepared a stipulated protective order designed to address the agencies' concerns regarding sensitive information and facilitate production of agency documents. The resulting proposed protective order (attached hereto as Exhibit A) contains provisions similar to those in the Supplemental Stipulated Protective Order entered in the SEC litigation for the same purpose. (See Dkt. No. 83 in 18-cv-01603 EJD).

Government counsel also contacted counsel for the Theranos Assignee. The Assignee had previously granted a waiver authorizing FDA and CMS to produce trade secrets and other confidential corporate information in response to Balwani's subpoena in the SEC civil case, but Assignee counsel informed the government that Balwani's lawyers had not requested a similar waiver applicable to the criminal case. The government remedied this omission and asked for such a waiver, obtaining the Assignee's agreement after providing the proposed protective order to Assignee counsel.

During the week of July 8, FDA and CMS responded to the Court's order with letters to all parties clarifying and revising their positions on the document requests. FDA's letter is attached hereto

as Exhibit B; CMS's letter is attached as Exhibit C. In those letters, both FDA and CMS confirm their intention to compile and produce documents in their possession responsive to all six of the categories chosen by Defendants. Both FDA and CMS have prepared initial document productions totaling more than 10,000 pages, which can be produced as soon as the protective order is entered and the Assignee's promised waiver is received.

According to their letters, the agencies will then continue to collect and review documents in response to the pending requests, producing all responsive materials other than limited categories of information consisting of attorney-client privileged communications, attorney work product, and third-party trade secrets / confidential information not covered by the Theranos Assignee waiver.[1] FDA has stated that it no longer intends to withhold Theranos-specific documents based on the deliberative process privilege, and CMS has similarly confirmed that it will not withhold documents on that basis.

CMS predicts that it can produce the documents it has already collected and loaded into its review database by mid-August. In the meantime, it is working to collect and load the rest of its potentially responsive documents for review. For its part, FDA estimates that its production of all responsive documents may take as long as six months. Defendants have objected to this schedule, and the prosecution shares the view that such a delay is unacceptable. The prosecution will make every effort to speed up the FDA's production of documents, up to and including serving its own Rule 17 subpoena on the agency if necessary. Today, both FDA and CMS represented to the prosecution that they are exploring options to complete their productions more quickly than the projections in their letters last week.

In sum, the following progress has been made since the June 28, 2019 hearing:

- Government drafted stipulated protective order incorporating input from FDA, CMS, Theranos Assignee, and defense counsel;
- Theranos Assignee agreed to provide a waiver allowing FDA and CMS production of

[1] FDA also states that it will withhold from production materials available from public media or similar organizations (which the government understands to apply to widely distributed news bulletin emails and similar documents) or materials containing "personal and private information" as well as information that could be used to identify a confidential informant. In recent conversations with government counsel, FDA has agreed not to withhold such personal and private information from its production and to rely on the proposed Supplemental Protective Order in producing such information.

Theranos confidential information under protective order;

- FDA and CMS confirmed agreement to search for and produce documents in their possession responsive to all requested categories;
- FDA and CMS prepared substantial initial productions that will be transmitted as soon as protective order is entered and waiver provided;
- FDA and CMS agreed not to withhold responsive documents regarding Theranos based on deliberative process privilege;
- FDA and CMS agreed not to withhold or redact personally identifying information in responsive documents;
- FDA agreed not to withhold responsive documents based on relevance objections; and
- CDPH completed email search confirming no additional responsive documents.

B. Status of Other Issues Addressed at June 28, 2019 Hearing

The Court's June 28, 2019 order states: "No later than July 12, 2019, the Government shall complete its Brady review of the SEC agent notes and memoranda relating to the interviews of Craig Hall and Bryan Tolbert and produce to the Defendants any *Brady* material contained therein." On July 9, 2019, the Government provided a disclosure to the defendants regarding the Hall and Tolbert interviews. The Government will review the remainder of the SEC notes for discoverable information and make any required disclosures to the defense. On July 9, 2019, the Government made available for the defense's review notes of interviews by FBI, USPIS, and FDA-CI criminal investigators.

C. Anticipated Next Steps

As described above, FDA and CMS have agreed to produce documents responsive to all of Defendants' requested categories once a supplemental protective order is entered in this case and the Theranos Assignee provides a waiver allowing production of confidential corporate information. In turn, the Assignee has agreed to give such a waiver upon entry of the same protective order. Accordingly, the government respectfully requests that the Court enter the attached Supplemental Protective Order. The Assignee will then give its waiver and FDA and CMS will transmit their initial document productions. The government has asked the agencies to produce their documents to all parties simultaneously to minimize delay. The agencies will then continue to collect, review, and produce

responsive documents on a rolling basis, with the government assisting in any way it can to ensure that the process is completed as quickly as possible.

The Court's June 28, 2019 order clearly conveyed the Court's view that the responsive documents currently held by FDA and CMS should be produced to the prosecution and the defense as soon as possible. Accordingly, the government believes that an additional Court order is unnecessary at this time. The government intends, however, to monitor the agencies' ongoing document productions—in particular, the agencies' efforts to complete their productions sooner than their initial projections—and will report to the Court immediately if a further order would help resolve this matter.

The Government will continue to make available for the defense's review any additional notes of interview by FBI, USPIS, and FDA-CI generated in the prosecution.

Finally, consistent with the Court's Order, the parties have jointly prepared a proposed pretrial schedule, which is attached hereto as Exhibit D.

II. Defendants' Statement

A. Agency Documents

The Court's inquiry at the June 28, 2019 hearing was clear: will the CMS and FDA ("the agencies") produce documents responsive to the six defense requests and, if so, when? On July 9 and 12, 2019, those agencies responded that they will gather *some but not all* documents responsive to the requests, on an unworkable timeline. Accordingly, a Court order is needed to ensure the defense will receive in a timely manner the documents they are entitled to under *Santiago* and *Bryan*. Only an order from this Court, not voluntary production by the agencies allowing them to collect some documents but not others, will ensure that all responsive documents from the agencies are produced, and safeguard defendants' constitutional rights to a fair trial and to present a complete defense.[2]

Notwithstanding the efforts set forth above, the government has been unable to obtain assurance from the agencies that they will produce *all* documents responsive to the six defense requests. To the

[2] To clarify the government's statement that the meet and confer conference was "in advance of the June 28, 2019 hearing," the actual date of that conference was April 5, 2019. The government did not request documents from the agencies until May 9, 2019, and they still have not complied.

contrary, rather than answer the simple question posed by the Court of whether they will produce the documents and when, the agencies dedicated a collective eight (8) pages (*See* Exhibits B and C) to describing what they have done to date to gather *some* responsive documents while failing to acknowledge that other responsive documents likely fall outside of those efforts.

The government's position during the drafting of this status report highlights that disconnect. The initial draft of the government's section of this report stated that the agencies confirmed that they would search for "*all* non-privileged documents in their possession responsive to any requested categories." (emphasis added) When defense counsel pointed out that the agencies' letters did not provide confirmation that *all* documents would be produced, and asked whether the government had independently obtained that assurance, the government conceded that the agencies had not actually agreed to produce *all* documents, and it revised the sentence to remove the reference to an agreement to produce "all non-privileged documents." *See* Exhibit E (7/15/19 email exchange between L. Wade and J. Bostic).

Moreover, the FDA says it will need up to six months to complete its production. CMS does not even give a timeframe for completing its production once it sets up a review database for some of the documents. Even the government agrees that the FDA's timeline, in particular, is "unacceptable" given the trial date in this case. The government does not even comment on CMS's vague timeline. The government's solution that it may have to resort to issuing a Rule 17 subpoena is, respectfully, unworkable, and likely only to lead to further delay. Moreover, the government's proposed solution is a concession that the agencies may not properly comply on their own without a Court order, and that the government anticipates that it may need help from the Court to achieve full compliance. This is after months of vague and inadequate correspondence from the agencies. The much simpler, direct, and appropriate solution is a Court order under Rule 16.

As a result, a Court order requiring collection and production of the six categories of documents, as well as specific deadlines for those productions, is necessary to ensure full and prompt compliance with the government's Rule 16 obligations. The government should not be allowed to satisfy its obligations by permitting the agencies to choose the custodians and categories of documents they prefer to collect and produce, and select the timeframes for production.[3]

B. SEC Notes.

By letter dated July 9, 2019, AUSA Robert Leach informed the defense of the contents of SEC notes regarding investor witness Craig Hall, pursuant to the government's *Brady* obligations. The defense is reviewing this material and will assess whether it believes further action is needed with respect to the SEC notes.

C. Agent Notes.

While the government has permitted the defense to access agent notes from witness interviews by reviewing them at the U.S. Attorney's Office, the government has refused to provide the defense with hard copies of these notes. On July 10, 2019, Mr. Balwani and his counsel conducted an in-person review of a subset of handwritten notes from the prosecution's witness interviews, and two days later, Mr. Balwani renewed his request that the government provide the defense with hard copies of these agent notes. *See* Exhibit F (7/12/2019 Letter from S. Cazares). Three attorneys from Mr. Balwani's defense team, and Mr. Balwani, spent almost 6 hours reviewing agent notes on July 10, but got through only a handful of them in that time due to the dense nature of the notes, very difficult and at times cryptic handwriting, and the need to constantly refer to the 302s to look for material discrepancies.

Nevertheless, even that session unearthed considerable undisclosed *Brady* material, including material variances between the contemporaneous, handwritten agent notes, and the resulting typewritten memoranda previously disclosed to the defense. As a result of the system the government is trying to set up here, Mr. Balwani has been put in the catch-22 position of having to reveal the defense's work

[3] Regarding the government's claim about the circumstances of contacting the Assignee for a protective order, Mr. Balwani does not agree with the accuracy of the government's characterization. However, Mr. Balwani is pleased that the agencies will no longer be able to claim this issue as a barrier to document production.

product and trial strategy to the government in order to obtain copies of agent notes, which is the only meaningful way he would be able to use this *Brady* material for trial preparation and at trial. If the defense identifies any *Brady* material in the notes, which it already has, the defense must get copies of all the notes to avoid having to reveal defense strategy and work product to the government by telling the government its selection of particular notes. The system set up by the government where the defense has to tell them which notes it thinks contain exculpatory evidence is thus unworkable and an improper intrusion into defense strategies and work product. There is no countervailing government interest that could possibly justify the government's continued refusal to provide copies of the agent notes to counsel and instead require the defense to continue to travel to review agent notes in-person at the U.S. Attorney's Office. *See* Exhibit F (7/12/2019 Letter from S. Cazares).

DATED: July 15, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
By 28 U.S.C. § 515

/s/
JEFF SCHENK
JOHN C. BOSTIC
ROBERT S. LEACH
Assistant United States Attorneys

DATED: July 15, 2019

/s/
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

DATED: July 15, 2019

/s/
JEFFREY B. COOPERSMITH
STEVE CAZARES
Attorneys for Ramesh "Sunny" Balwani

EXHIBIT A

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CASE NO. 18-CR-00258 EJD STIPULATION AND [PROPOSED] SUPPLEMENTAL PROTECTIVE ORDER

The United States of America, by and through ADAM A. REEVES, Attorney for the United States Acting Under Authority Conferred by 28 U.S.C. § 515, and JEFF SCHENK, JOHN C. BOSTIC, and ROBERT S. LEACH, Assistant United States Attorneys for the Northern District of California, and the defendants, ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, and their attorneys, KEVIN DOWNEY and LANCE WADE of Williams & Connolly for HOLMES, and JEFFREY B. COOPERSMITH and STEPHEN A. CAZARES of Davis Wright Tremaine for BALWANI, hereby stipulate and jointly request that the Court issue a supplemental Protective Order in this case as described below.

The parties stipulated to, and the Court entered, a Protective Order in this case on or about July 2, 2018 (Docket #28) ("the Original Protective Order"). During the course of its investigation, the United States has obtained materials from various government agencies, including the Food and Drug Administration ("FDA") and the Centers for Medicare & Medicaid Services ("CMS"), and may obtain additional materials from the foregoing agencies or from other similar government agencies. These materials may contain information that the government considers confidential corporate information, trade secrets, Protected Health Information (PHI, as defined in HIPAA), or protected by certain privileges and doctrines, such as work product and deliberative process. Accordingly, the parties agree that a Supplemental Protective Order is necessary to govern access to and use of such "Government Agency Documents," which shall include any documents produced by the government bearing a bates number prefix containing "FDA" or "CMS" and bearing the legend "FDA/CMS – CONFIDENTIAL," or any other documents the government identifies in writing as Government Agency Documents that are in need of protection under the terms of this Supplemental Protective Order. Defendants agree to the designation of documents as protected under this Supplemental Protective Order or the Original Protective Order for the purpose of facilitating production of documents without delay caused by a need for a line by line review of documents, and not based on any agreement or concession that any documents are worthy of such protection.

Therefore, the parties stipulate and agree as follows:

1. Each reference to "Private Documents" in paragraphs 1 through 4 and 6 of the Original Protective Order shall apply to Government Agency Documents.

ADDITIONAL PROTECTIONS FOR PHI IN CMS DOCUMENTS

2. Pursuant to 45 C.F.R. § 164.512 et seq. and for purposes of compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and subject to the provisions of this Protective Order, legal counsel in this case, the employees and agents of each party, and all non-party Covered Entities, as that term is defined in HIPAA, are expressly and specifically authorized to use or disclose Protected Health Information (PHI), as that term is defined in HIPPA, in accordance with this order to:

a) comply with the discovery obligations and requests made pursuant to the Federal Rules of Criminal Procedure in this case seeking PHI;

b) request interviews or depositions and interview, depose, or respond in interviews or depositions in which PHI might be disclosed;

c) prepare briefs and other materials for the Court so long as such materials are treated in accordance with this Protective Order; and

d) disclose PHI to a party's expert regardless of whether the expert is a consulting or testifying expert.

3. The intent of the additional protections for PHI is to authorize the use and disclosure of PHI in accordance with 45 C.F.R. § 164.512 and the terms of this Protective Order. To the extent that the uses and disclosures of PHI authorized under this Protective Order may be permitted under other provisions of the HIPAA Privacy Rule, such uses and disclosures shall be made pursuant to and in accordance with 45 C.F.R. § 164.512(e). This paragraph shall not be read to authorize uses and disclosures of PHI that are not otherwise authorized under this Protective Order.

4. Pursuant to 5 U.S.C. § 552a(b)(11), this Protective Order authorizes CMS to release Privacy Act-protected information covered by this Protective Order, without the consent of the subject individual.

CERTIFICATIONS AND MISCELLANEOUS

5. Prior to receiving access to any Government Agency Documents, each Defense Team member shall sign a copy of the attached Certification. By signing the Certification, each Defense Team member acknowledges that:

a) She or he has reviewed the Original Protective Order as well as this Order;

b) She or he understands the contents of those Orders;

c) She or he will access and use Government Agency Documents only as permitted by the terms of those Orders; and

d) She or he understands that failure to abide by those Orders may result in sanctions by this Court and she or he submits to the jurisdiction of the Court for the purpose

of enforcing those Orders and imposing any sanctions for their violation.

6. Defense counsel will maintain a copy of each signed Certification. The United States shall have no access to these signed copies without further order of the Court.

7. Any pleadings that reveal the contents of Government Agency Documents—either by attaching copies of such documents or by referencing their content—shall be filed under seal or redacted to prevent the disclosure of such contents.

8. Any disputes concerning this Stipulation and Protective Order shall be resolved by this Court only after defense counsel and counsel for the United States have first conferred and attempted to resolve the dispute.

9. Additionally, in the event either defendant seeks to challenge the designation of a document under this Supplemental Protective Order, or obtain a judicial ruling permitting broader disclosure of the contents of such a document, that defendant shall notify government counsel in this case to inquire whether the United States or any interested person or party objects to public disclosure of a specific document. Upon receipt of such notice, government counsel shall determine whether there is any objection to the requested lifting of protections under this Supplemental Protective Order for the identified document. Government counsel shall provide an email response to any such inquiries by defendants promptly, but no later than ten business days after receiving the inquiry, including identification of any requested redactions of the identified document. In the event government counsel fails to respond to such inquiry by defendants within 10 days, relief from the protections of this Supplemental Protective Order for the identified document shall be automatic.

10. As this Order does not directly address the use or introduction of Government Agency Documents at trial, the parties agree to meet and confer in advance of trial regarding appropriate procedures to protect sensitive information in such documents. By stipulating to this Supplemental Protective Order, the defendants do not waive any right they may have to petition the Court *ex parte* and *in camera* to challenge or remove the designation of a document under this Supplemental Protective Order, or the Original Protective Order, to facilitate the appropriate use of that document at trial. Conversely, the government does not concede that any such issues should be addressed *ex parte*.

11. Counsel for the defendants shall notify CMS of the completion of this case so that the agency can complete its disclosure tracking obligations. Such notification should be sent to DataUseAgreement@cms.hhs.gov and CMS counsel and a copy of this Order should be attached.

12. The parties stipulate to this Order without prejudice to their ability to seek to modify the terms of the Order at a future date.

DATED: July 15, 2019

Respectfully submitted,

ADAM A. REEVES
Attorney for the United States
Acting Under Authority Conferred
by 28 U.S.C. § 515

/s/
JEFF SCHENK
JOHN C. BOSTIC
ROBERT S. LEACH
Assistant United States Attorneys

DATED: July 15, 2019

/s/
KEVIN DOWNEY
LANCE WADE
Attorneys for Elizabeth Holmes

DATED: July 15, 2019

/s/
JEFFREY B. COOPERSMITH
STEPHEN A. CAZARES
Attorneys for Ramesh "Sunny" Balwani

SO ORDERED.

DATED: _____

_____
HONORABLE EDWARD J. DAVILA
United States District Court Judge

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	CASE NO. 18-CR-00258 EJD CERTIFICATION REGARDING COMPLIANCE WITH PROTECTIVE ORDER

The undersigned acknowledges that she or he has received copies of the Original Protective Order (Dkt. No. 28) and the Supplemental Protective Order in the case of UNITED STATES v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, CR 18-258-EJD, and has read, understands, and agrees to the terms of both Orders, and hereby submits to the jurisdiction of the United States District Court for the Northern District of California for the purposes of enforcement of the terms and punishment of any violations thereof.

Date: _____

_____
Signature

_____
Printed Name

EXHIBIT B

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
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July 9, 2019

Via Email

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Jeffrey B. Coopersmith
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Kevin M. Downey
Williams & Connolly LLP
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Re: Document Request – *United States v. Elizabeth Holmes & Ramesh Balwani*, 18-CR-00258 EJD (N.D. Cal.)

Dear Messrs. Bostic, Coopersmith, and Downey:

Pursuant to the June 28, 2019 Order in the above-captioned action directing the United States Food and Drug Administration ("FDA") to provide the parties with specific information regarding the documents it agrees to produce or objects to producing in response to the document requests made by the Government on behalf of Defendants, FDA replies as follows.

FDA is, and has been, working diligently to collect, process, review, and ultimately produce all documents responsive to all six categories requested by the parties. FDA's collection and review began in response to an earlier subpoena by Defendant Balwani's counsel, Mr. Coopersmith, in the separate but related matter *Securities and Exchange Commission v. Ramesh "Sunny" Balwani*, Civil Action No. 5:18-cv-01603 (N.D. Cal.) (the "SEC matter"). That subpoena requests, among other items, "all documents and communications referring or relating to Theranos, Holmes, or Balwani" (Balwani SEC RFP No. 1). Because all six categories of documents requested in the above-captioned matter are subsumed by the subpoena issued in the SEC matter, FDA has effectively been collecting, processing, and reviewing documents responsive to the six categories even prior to receiving the requests by the U.S. Department of Justice ("DOJ").

To date, in addition to the over 40,000 pages that FDA previously produced to DOJ that were forwarded to Defendants, *see* Dkt. No. 67, at 3, FDA has collected over 19,000 documents[1] from more than 45 custodians located in 8 FDA offices, including the Office of

[1] FDA previously stated that it had collected over 62,000 documents in response to the subpoena in the SEC matter, but then discovered that many of those documents were false hits containing the word "Holmes" but that were unrelated to Defendant Holmes or Theranos. New searches were run to exclude the false hits, which account for the new and lower number of potentially responsive documents.

U.S. FOOD & DRUG ADMINISTRATION

Office of the Chief Counsel
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Legislation, the Office of Media Affairs, the Office of Regulatory Affairs, the Office of the Chief Counsel, and the following offices in FDA's Center for Devices and Radiological Health ("CDRH"): the Office of the Center Director; the Office of Communication and Education; the Office of Surveillance and Biometrics; and the Office of In Vitro Diagnostics and Radiological Health. Although FDA has no practicable electronic mechanism by which it can isolate the documents in its present collection that correspond to the six categories requested in the above-captioned action,[2] to the extent FDA can prioritize documents from custodians likely to have documents responsive to the six categories, it will do so. For example, FDA will prioritize documents from its Office of Media Affairs, which is the office most likely to have documents responsive to Category 1 of Defendants' motion to compel, which seeks all communications regarding Theranos between the government and the Wall Street Journal (*see* Dkt. No. 67).

FDA is committed to continue working cooperatively with the parties to provide them non-privileged documents responsive to the six requested categories in the most efficient manner possible. To that end, FDA will produce documents responsive to all six categories and is waiving its deliberative process privilege for Theranos-specific documents.[3]

FDA will continue to process the documents it has collected and will produce to the parties in the above-captioned matter all Theranos-related documents, including those responsive to the six categories requested in this matter, subject to the following limitations, which were discussed in greater detail in my June 7, 2019 letter to Mr. Bostic (Dkt. No. 79-4):

1. Most importantly, FDA is prohibited by law from producing to the parties in the above-captioned matter documents containing Theranos's trade secret and/or confidential commercial information without (1) a waiver from Theranos's assignee or (2) a court order directing FDA to produce Theranos's trade secret and confidential commercial information to the parties. *See* 21 U.S.C. § 331(j); 21 U.S.C. § 360j(c); 18 U.S.C. § 1905; 21 C.F.R. § 20.61. In the SEC matter, Theranos's assignee recently provided a waiver permitting FDA to produce Theranos's trade secret and confidential commercial information in response to the subpoena issued by Defendant Balwani and pursuant to the supplemental protective order entered

[2] FDA does not currently have the capability to extract a narrower set of documents from its current collection and exclude those from further review for the SEC matter. In other words, were FDA to electronically isolate the documents in its collection that are potentially responsive to the six categories, FDA would have to review those documents a second time to respond to Defendant Balwani's subpoena in the SEC case. Accordingly, by proceeding with its processing, review, and production of its broader collection of Theranos-related documents, FDA is undertaking the most efficient route toward resolving the parties' requests in both related matters.

[3] FDA has not waived its deliberative process privilege for non-Theranos-specific documents related to the agency's non-final laboratory developed test ("LDT") policy and draft guidance, and deliberations regarding the same.

FDA U.S. FOOD & DRUG ADMINISTRATION

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in that case.[4] That waiver permits FDA to review documents more quickly because it no longer needs to review for, and redact, Theranos's trade secret and confidential commercial information.[5] Indeed, FDA expects to make a production of Theranos-related documents to Defendant Balwani's counsel this week in the SEC matter. That production will consist of over 350 documents and 5,500 pages. FDA can provide the parties in the above-referenced matter those documents as soon as it obtains a waiver from Theranos's assignee or a court order directing FDA to produce the documents that it produces to Defendant Balwani's counsel in the SEC matter to the parties in the above-captioned action. FDA estimates that it can complete its entire production of the documents it has collected in response to the subpoena in six months if there is a waiver from Theranos's assignee or a court order directing the agency to produce documents to the parties in the above-captioned action; that timeframe will be more than twice as long without a waiver or court order, because FDA will have to re-review the documents and redact Theranos's trade secret and commercial confidential information from them before they can be produced to the parties in the above-referenced matter.

2. FDA intends to redact third-party trade secret and confidential commercial information from the responsive documents as required under the law. 21 U.S.C. § 331(j); 21 U.S.C. § 360j(c); 18 U.S.C. § 1905; 21 C.F.R. § 20.61.

3. To the extent a document is privileged or otherwise protected (including but not limited to attorney-client communications and attorney work product, personal and private information, and information that could be used to identify a confidential informant, if any), FDA will redact it or, if it is not segregable, withhold it in its entirety, except that it will release the document or a segregable portion of it, as applicable, to the extent it is subject to FDA's deliberative process privilege waiver.

4. To the extent a document is available from public media or similar organizations (including but not limited to Bulletin Intelligence, GenomeWeb, The Gray Sheet, PharmaVOICE, POLITICO Pulse, and Google Alerts) and does not otherwise include commentary by FDA employees (such as, for example, an employee forwarding a news article and commenting on the article in the body of the email), FDA will not produce it, as such items are available to the parties by other, less burdensome means.

5. To the extent FDA identifies a document that it has already produced to DOJ and which DOJ has produced to the parties in the above-captioned action, FDA will not produce that document again. Of course, given the limitations of FDA's technology,

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[4] The waiver from Theranos's assignee in the SEC case followed multiple requests to Defendant Balwani's counsel and counsel to Theranos's assignee over several months and protracted negotiations regarding a protective order requested by the assignee.

[5] Of course, FDA still must review for, and redact, third-party trade secret and confidential commercial information. However, FDA expects that there will be little of that information among the collected documents.

U.S. FOOD & DRUG ADMINISTRATION

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Silver Spring, MD 20993-0002

outlined in our June 7 letter, it is likely that the productions will include duplicates of previously-produced documents.

6. FDA will limit its search for responsive documents to the date range January 1, 2010 through June 30, 2018, which is the date range for which FDA collected documents pursuant to Defendant Balwani's subpoena in the SEC matter. Such timeframe is more than reasonable, as it encompasses the timeframe of the single allegation related to FDA in the Superseding Indictment (late 2013 through 2014), *see* Dkt. No. 39, at ¶ 12(F); it is the date range selected by Defendant Balwani in his subpoena for the SEC matter; and it reduces the undue burden on FDA that would result from the original, non-time-limited request.

To summarize, FDA is not withholding responsive documents based on a determination of relevance, and it is not withholding documents that relate specifically to Theranos on the basis of the deliberative process privilege. It does, however, need to review the collected documents for responsiveness as well as the other privileges and protections discussed above.

I trust that this letter conveys the information that the Court directed FDA to provide to the parties. FDA will continue to work as expeditiously as possible to provide the parties with the requested material, as set forth above.

Sincerely,

Marci B. Norton

Marci B. Norton
Senior Counsel

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

July 12, 2019

Sent By Email
John C. Bostic
Assistant United States Attorney
Northern District of California
150 Almaden Boulevard, Suite 900
San Jose, California 95113
John.Bostic@usdoj.gov

Jeffrey B. Coopersmith
Davis Wright Tremaine LLP
920 Fifth Avenue Suite 3300
Seattle WA 98104
jeffcoopersmith@dwt.com

Kevin Downey
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005
kdowney@wc.com

Re: Document Access Request - *United States v. Elizabeth Holmes and Ramesh Balwani*, 18-CR-00258 EJD

Dear Messrs. Bostic, Coopersmith, and Downey:

This letter responds to the Court's June 28, 2019 order in the above-captioned action instructing the Centers for Medicare & Medicaid Services (CMS) to provide the parties with specific information regarding the documents the agency agrees to produce or objects to producing in response to the document requests made by the Government on behalf of Defendants.

In my previous letter to Mr. Bostic dated June 10, 2019, CMS agreed to provide documents in the agency's possession between September 1, 2013 and December 31, 2016[1] that are responsive to the six categories of documents requested and that are not protected by the attorney-client or work product privileges. The following is a summary of the steps CMS has taken to identify, collect, and review responsive documents.

CMS understands that the parties are currently negotiating a proposed Supplemental Protective Order that will govern CMS documents produced in this case and that Mr. Bostic is working to obtain a waiver from Theranos's assignee permitting CMS to disclose Theranos's trade secret and confidential commercial information to the parties in response to this document request. Once the Court enters the Supplemental Protective Order and the waiver is obtained, CMS will promptly

[1] Mr. Balwani's counsel previously agreed to narrow the time period relevant to Mr. Balwani's subpoena to CMS in *SEC v. Balwani*, Case No. 18-cv-01602-EJD to September 1, 2013 and December 31, 2016.

provide Mr. Bostic with 5,014 pages that fall within the following categories of external communications responsive to the document request as follows.

- Communications between the CMS Office of Communications and the media about Theranos, including communications between the agency and John Carreyrou or the Wall Street Journal. The CMS Office of Communications coordinates requests for information from members of the media and provides responses on behalf of the agency. These documents are responsive to Document Request No. 1.

- Communications between CMS (the Clinical Lab group and CCSQ Management) and Theranos. The CMS Division of Clinical Laboratory Management and Quality (the Clinical Lab group) is responsible for Clinical Laboratory Improvement Amendment (CLIA) programs. Two CMS employees from this group performed the 2015 CLIA survey of Theranos. The Clinical Lab group is part of the CMS Center for Clinical Standards and Quality (CCSQ) and some members of CCSQ management were involved with the Theranos matter after the 2015 survey was performed. These documents are responsive to Document Request No. 2.

- Communications between the Clinical Lab group and the American Association of Clinical Chemistry (AACC). These documents are responsive to Document Request No. 3. The CMS Clinical Lab group does not generally communicate with third parties about the CLIA compliance of particular laboratories. The agency conducted a limited search for communications between the CMS Clinical Lab group and LabCorp, Quest Diagnostics, or the AACC to confirm this practice. The search produced a few emails to or from AACC that are all form marketing emails or emails about attending the AACC Annual Scientific Meeting. These results confirm that CMS did not communicate with third parties about Theranos's lab compliance with CLIA and, therefore, the agency would not have additional documents responsive to Document Request No. 3.

- Documents from the California Department of Public Health's California Laboratory Field Services (CDPH) related to the federal 2013 Theranos CLIA Survey. These documents are responsive to Document Request No. 6. CDPH conducted a search and no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist. *See* Attachment A, Declaration of Donna McCallum, July 11, 2019.

Internal communications were redacted from the categories of documents listed above because they were originally reviewed for production in response to a subpoena in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. CMS has produced these redacted documents to Mr. Balwani in the civil matter. Subsequent productions will include revised versions of materials where internal communications were previously redacted, but redactions made to protect information covered by the attorney-client or work product privileges will remain. CMS does not intend to withhold information that may be protected by the deliberative process privilege.

CMS also produced communications between the Clinical Lab group and the U.S. Food and Drug Administration (FDA) about Theranos to Mr. Balwani in *SEC v. Balwani*, Case No. 18-cv-01602-EJD. Once the Court enters the Supplemental Protective Order and the Theranos assignee provides a waiver, CMS will promptly produce those documents to Mr. Bostic. CMS also identified and reviewed additional CMS communications with the FDA about Theranos and is processing those communications for production. The estimated production date is the week of July 15, 2019. These documents are responsive to Document Request No. 4.

CMS has made significant efforts to identify, collect, review, and produce non-privileged internal email responsive to Document Request Nos. 1, 2, 4, and 6. These efforts are explained in detail below. Although CMS cannot control the amount of time it will take to load data into the Relativity review database, process the data so it is ready for review, or process the data for production, the agency has used its best efforts to provide an estimated time line. The time line assumes that a Supplemental Protective Order is entered by the Court and the Theranos assignee grants a waiver to allow CMS production of these documents.

- Internal email from employees in the CMS Office of Communications who dealt with media contacts about Theranos have already been collected and loaded into the review database. CMS is currently conducting a review for documents protected by the attorney-client and work product privileges. CMS estimates that these documents will be produced to Mr. Bostic by August 16, 2019. These documents are responsive to Document Request No. 1.

- Some internal email from employees in the Clinical Lab group and CCSQ Management have already been collected and loaded into the review database. CMS is currently conducting a review for documents protected by the attorney-client and work product privileges. CMS estimates that these documents will be produced to Mr. Bostic by August 16, 2019. These documents could be responsive to Document Request Nos. 1, 2, 4, and 6.

- In addition to the email previously collected, CMS has also started the process of collecting and identifying email from the Clinical Lab group, CCSQ Management, and FOIA personnel to provide a complete set of internal communications about Theranos between September 1, 2013 and December 31, 2016. CMS IT has almost completed collecting documents from these custodians and will work to identify the potentially responsive set of documents. The responsive set of documents will then need to be exported and shipped to the Relativity database staff. The CMS request to upload the data is then put into a queue and CMS has no control over how quickly the data is loaded. The average load time has recently been thirteen work days. Once the data is loaded, further processing is needed to get to the documents that CMS will need to review. The average time for data analysis and processing has recently been eight work days. CMS will not know the quantity of documents until this work is complete. CMS estimates that this data will be identified and loaded into the review database by August 23, 2016. Once the data is loaded, CMS will be better able to estimate how long it will take to review the documents for information protected by the attorney-client and work product privileges and produce them. CMS is exploring methods to potentially decrease the time it will take to produce these documents. CMS will provide a status update to the parties promptly after CMS knows the quantity of documents to review. These documents could be responsive to Document Request Nos. 1, 2, 4 and 6.

CMS does not have documents responsive to Request No. 5. While CMS interacts with and supports law enforcement, the agency does not serve a criminal law enforcement function and, therefore, it does not create or retain Reports of Investigation (ROIs) memorializing government communications with witnesses.

CMS is committed to working with you to produce documents responsive to your requests as detailed above. Please contact CMS counsel Lindsay Turner to discuss this matter further.

Sincerely,

Karen W. Dyer

Karen W. Dyer
Director
Division of Clinical Laboratory Improvement and Quality
Centers for Medicare & Medicaid Services

DECLARATION

I, Donna McCallum, hereby declare under penalty of perjury under the laws of the State of California that the following statements are true to the best of my knowledge and belief:

1. I am the Section Chief for the Clinical Laboratory Improvement Amendment (CLIA) Section for the California Department of Public Health's Laboratory Field Services (LFS). I have knowledge of the facts stated herein.
2. On June 3, 2019, I declared that LFS had in its custody specified Federal Centers for Medicare and Medicaid services (CMS) documents regarding the 2013 CLIA survey of Theranos.
3. In that declaration, I also stated that LFS had initiated an email search to verify that no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist and that LFS would confirm with CMS once the search inquiry is completed.
4. LFS has completed its email search inquiry and confirms that no email communications with CMS regarding the routine 2013 CLIA survey of Theranos exist.

I declare under penalty of perjury that the foregoing is true and correct.

Donna McCallum
Declarant Signature

7/11/2019
Date

EXHIBIT D

PROPOSED PRETRIAL SCHEDULE

Date	Event
Monday, September 16, 2019	The Government shall complete its Rule 16(a) disclosures (except expert disclosures). The Government shall remain obligated to produce any Rule 16(a) material it subsequently discovers.
Tuesday, October 15, 2019	All pretrial motions pursuant to Rule 12(b)(3)(A)-(D) are to be filed.
Tuesday, November 12, 2019	Responses to Rule 12(b)(3)(A)-(D) motions due.
Tuesday, November 25, 2019	Replies in support of Rule 12(b)(3)(A)-(D) motions due.
Monday, December 16, 2019	Hearing on Rule 12(b)(3)(A)-(D) motions.
Monday, February 3, 2020	The Government shall complete its disclosure of *Jencks* materials. The Government shall remain obligated to produce any *Jencks* materials it subsequently discovers.
Friday, March 6, 2020	The Government shall serve a summary under Rule 16 for each expert witness that it intends to call at trial in its case-in-chief.
Friday, March 6, 2020	The Government shall provide notice of any evidence of other crimes, wrongs or acts which the Government intends to offer under Federal Rule of Evidence 404(b).
Wednesday, April 29, 2020	Each defendant shall serve a summary pursuant to Rule 16 for each expert witness that defendant intends to call at trial in the defendant's case-in-chief.
Friday, May 1, 2020	Each defendant shall complete the defendant's Rule 16 disclosures other than expert disclosures.
Friday, May 1, 2020	The Government shall serve witness and exhibit lists for its case-in-chief. The Government shall identify any statement the Government intends to offer under Federal Rule of Evidence 801(d)(2)(E).
Wednesday, May 13, 2020	The Government shall serve a summary pursuant to Rule 16 for each expert witness that it intends to call at trial in rebuttal to expert testimony offered by any defendant.

Friday, May 15, 2020	Each defendant shall serve witness and exhibit lists for the defendant's case-in-chief.
Friday, May 22, 2020	Motions *in limine* and motions relating to experts due.
Friday, May 22, 2020	Proposed jury instructions, juror questionnaire, and voir dire questions due.
Monday, June 8, 2020	Responses to motions *in limine* and motions relating to experts due.
Monday, June 8, 2020	The parties shall file a pretrial conference statement addressing the matters set forth in Local Rule 17.1-1. The Government shall advise the Court that it has produced all *Brady* and *Giglio* information in its possession and will continue to produce any the government subsequently discovers.
Monday, June 22, 2020	Replies in support of motions *in limine* and motions relating to experts due.
Monday, July 13, 2020	Pretrial Conference
Tuesday, July 28, 2020	Jury Selection
Tuesday, August 4, 2020	First Day of Trial

EXHIBIT E

McDowell, Amanda

From: Bostic, John (USACAN) <John.Bostic@usdoj.gov>
Sent: Monday, July 15, 2019 6:29 PM
To: Wade, Lance; Cazares, Steve; Schenk, Jeffrey (USACAN); Leach, Robert (USACAN)
Cc: Coopersmith, Jeff; Gorton, Kelly; Byer, Ben; McDowell, Amanda; Chen, Michelle; Trefz, Katherine; Roper, Seema Mittal; Downey, Kevin
Subject: RE: US v. Holmes et al - Supplemental PO - Revised

[EXTERNAL]

Lance,

I take your point on the italicized language. I edited a similar sentence earlier in the draft but left that one as-is as an oversight. We will revise that sentence to read: "FDA and CMS confirmed agreement to search for and produce documents in their possession responsive to all requested categories."

John

From: Wade, Lance <LWade@wc.com>
Sent: Monday, July 15, 2019 6:23 PM
To: Bostic, John (USACAN) <jbostic@usa.doj.gov>; Cazares, Steve <SteveCazares@dwt.com>; Schenk, Jeffrey (USACAN) <JSchenk@usa.doj.gov>; Leach, Robert (USACAN) <RLeach@usa.doj.gov>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>; Byer, Ben <BenByer@dwt.com>; McDowell, Amanda <AmandaMcDowell@dwt.com>; Chen, Michelle <MChen@wc.com>; Trefz, Katherine <KTrefz@wc.com>; Roper, Seema Mittal <smroper@wc.com>; Downey, Kevin <KDowney@wc.com>
Subject: RE: US v. Holmes et al - Supplemental PO - Revised

Counsel:

Your draft states that the "FDA and CMS confirmed agreement to search for and produce *all* non-privileged documents in their possession responsive to any requested categories." (Emphasis added). That confirmation is not provided in the correspondence from the agencies that was sent to defense counsel. We write to confirm that you have independently received that conformation from the agencies. Given that this (and other) new information was provided to us at this late hour, with a filing due, we request an immediate response to this inquiry.

Respectfully,

Lance Wade
Williams & Connolly LLP
725 Twelfth Street, N.W., Washington DC 20005
(P) 202-434-5755 | (F) 202-434-5029
lwade@wc.com | www.wc.com/lwade

From: Bostic, John (USACAN) <John.Bostic@usdoj.gov>
Sent: Monday, July 15, 2019 9:00 PM
To: Cazares, Steve <SteveCazares@dwt.com>; Wade, Lance <LWade@wc.com>; Schenk, Jeffrey (USACAN) <Jeffrey.B.Schenk@usdoj.gov>; Leach, Robert (USACAN) <Robert.Leach@usdoj.gov>
Cc: Coopersmith, Jeff <JeffCoopersmith@dwt.com>; Gorton, Kelly <KellyGorton@dwt.com>; Byer, Ben <BenByer@dwt.com>; McDowell, Amanda <AmandaMcDowell@dwt.com>; Chen, Michelle <MChen@wc.com>; Trefz,

EXHIBIT F

Davis Wright Tremaine LLP

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Stephen A. Cazares
213.633.8607 tel
213.633.6899 fax

stevecazares@dwt.com

July 12, 2019

VIA EMAIL

Jeffrey B. Schenk
John C. Bostic
Robert Leach
Assistant United States Attorneys
U.S. Attorney's Office, Northern District of California
150 Almaden Boulevard. Suite 900
San Jose, CA 95113

Re: *United States v. Holmes and Balwani*, Case No. CR-18-00258-EJD (N.D. Cal.)

Dear Counsel:

We write on behalf of Mr. Balwani to request that the government reconsider its prior refusal to provide the defense with copies of agent handwritten notes of witness interviews.

On May 20, 2019, and again on June 10, 2019 when we discussed the issue before court, the government declined to produce to the defense copies of handwritten agent notes, taken contemporaneously during witness interviews, from which typewritten memoranda that have been disclosed to the defense were prepared, often weeks and months after the witness interviews. Instead, you agreed to make the agent notes available for in-person review at the government's offices beginning July 1, 2019. On June 12, 2019, in the United States' Opposition to Defendants' Motion to Compel, you advised the Court that "the government has agreed to make available to the defense agent notes of witness interviews, so that the defense can conduct its own review and *confirm the absence of any material inconsistencies*."

On July 10, 2019, three attorneys for Mr. Balwani, and Mr. Balwani himself, began the review of the 848 pages of handwritten notes at the government's offices in San Francisco. This review identified numerous "material inconsistencies" between the notes and resulting memoranda, thereby demonstrating why mere review of the notes in the government's offices is impractical and burdensome on Mr. Balwani's right to evidence necessary and material to preparing his defense under Rule 16 and *Brady v. Maryland*.

First, review and comparison of handwritten notes (often with very difficult handwriting) against the resulting typewritten reports and referenced exhibits used in the interviews is extremely laborious, time-consuming, and physically demanding work. Mr. Balwani and his

three attorneys spend at least 19.5 person hours from 10 a.m. to 4 p.m., not counting a lunch break, reviewing the notes at the government's offices. In this time frame, we were able to get through only a handful of notes. At this pace, even doing one full pass through all the notes will take hundreds of hours and result merely in our own notes of agent notes of witness interviews which would be of limited use at trial.

Second, review of agent notes at the government's offices increases the amount of time and expense to Mr. Balwani to obtain access to materials necessary to the preparation of the defense. As you know, most of Mr. Balwani's attorneys work out of Seattle and Los Angeles, requiring travel time and expense to review the notes at the government's offices. Such costs will be even more substantial for counsel to Ms. Holmes, who work out of Washington, D.C.

Third, our initial review identified material variances between the contemporaneous, handwritten agent notes, and the resulting typewritten memoranda previously disclosed to the defense. Some of these variances identified in our initial review constitute impeachment and other material subject to the government's obligations under *Brady*. For example, we identified variance between the agent notes and resulting memoranda that appear to impact alleged material misrepresentations contained in the indictment. Thus, any requirement that Mr. Balwani identify *Brady* material within the agent notes to the government in order to obtain copies of the notes for use at trial, as the government has previously suggested, would require the disclosure of defense strategy and work product protected by the Sixth Amendment that is not warranted by any countervailing government interest in refusing to produce copies of notes. This reason alone requires the government to provide copies of all agent notes to the defense.

Fourth, our identification of *Brady* information in the agent notes reviewed so far requires the government to provide copies of all of the notes to the defense because the only way to use the information contained in the handwritten notes, which are subject to *Brady*, would be to question and/or confront either the agent or witness with the notes at trial. This is not possible using our own notes of the notes of the witness interviews. Accordingly, government failure to provide copies of all agent notes in light of this discovery of *Brady* information within the notes would undermine Mr. Balwani's right to due process and a fair trial under *Brady* and the Fifth Amendment.

Fifth, our examination and comparison of handwritten notes with the resulting interview memoranda has demonstrated that, given the complexity of the subject matter of this case, audio recording of witness interview sessions would be the best practice to avoid inaccurate reporting of witness statements going forward. For this reason, we request that the government audio record any further witness interviews or sessions in which witnesses make statements relevant to this case.

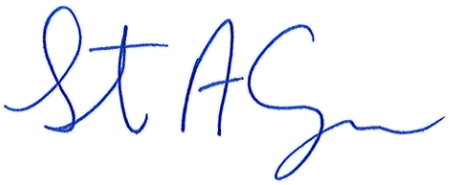
Sixth, due to the volume of handwritten notes and number of witness interviews, in order to permit tracking and verification that all handwritten notes of interviews have been disclosed to the defense, we request an index of the notes identifying witnesses and dates of interviews.

Finally, some of the copies of notes in the binders we reviewed on July 10 were such poor quality copies that we could not read them at all. We request that all copies be of the best possible quality so that we can read them.

We look forward to your prompt response to this renewed request that the government provide copies to the defense of all contemporaneous handwritten agent notes of interviews.

Very truly yours

Davis Wright Tremaine LLP



Stephen A. Cazares

cc: Jeffrey B. Coopersmith
Lance Wade (for Ms. Holmes)